K122435

510(k) Summary

DEC 2 0 2012

A. Date Prepared:

August 8, 2012

B. 510(K) Owner:

Nova Biomedical Corporation
200 Prospect St.
Waltham, MA 02454 USA
Contact Person: Paul W. MacDonald
Phone: 781-894-0800
Fax Number: 784-891-4806
Registration Number: 1219029

C. Device Information

1. Proprietary Name:

Nova One Blood Glucose Monitor

2. Common Or Usual Name:

Blood Glucose Monitor

3. Classification Name:

System, Test, Blood Glucose

4. Classification:

Class II (assay) and Class I, Reserved Controls

5. Product Codes:

NBW, Blood Glucose Test System, Over-the-Counter
LFR, Glucose Dehydrogenase
JJX, Single (specified) analyte controls (assayed and unassayed)

6. Regulatory Section:

21 CFR 862.1345, Glucose Test System
21 CFR 862.1660, Quality Control (assayed and unassayed)

7. Panel:

Clinical Chemistry (75)

D. Intended Use:

The Nova One Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous, arterial and fresh capillary whole blood from the finger and forearm. It is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a professional healthcare setting as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use, auto-disabling lancets. The Nova One Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on neonates. Alternative site testing on the forearm should be used only during steady-state blood glucose conditions.

Nova One Blood Glucose Test Strips are for use with the Nova One Blood Glucose Monitors for quantitatively measuring glucose in venous, arterial and fresh capillary whole blood from the finger and forearm.

E. Limitation Statement:

Venous and arterial whole blood collected in heparin tubes or syringes may be used for testing. EDTA is not recommended for use with the Nova One. Mix blood thoroughly before testing.

F. Device Description:

Nova One Blood Glucose Monitor

The monitor is a hand-held testing device that works in conjunction with Nova One glucose test strips to measure glucose in a whole blood sample. Monitor operation is self-prompting using three user interface buttons. In addition to measuring glucose, the monitor also stores patient test and quality control test data.

The self-prompting menu system is navigated by means of a three-button keypad. It offers audible feedback for user inputs, and audible and/or visual feedback for prompts and user alerts.

A "battery low" warning will alert the user to change the batteries. Battery charge state information is available on the "monitor status screen". The user can select the auto shutoff option to conserve power when the monitor is not in use. Test data and monitor setup information will be stored in a non-volatile format to prevent data loss.

Nova One Blood Glucose Test Strips

The test strips contain a reaction layer that contains a glucose-enzyme (greater than 1.0 IU) and ferricyanide as a mediator and will utilize glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) chemistry. The test strip is touched to a drop of blood to initiate the test process. The strip is designed such that when a drop of blood is touched to the end of the strip, the blood is drawn into the reaction space via capillary action. A simple one-step process provides a blood glucose result. Ten test strips will be provided with the meter kit and will also be available separately in vials of 25 strips. These test strips are manufactured by Nova Biomedical and identical to those cleared for market with the predicate Nova Max One Blood Glucose Monitor System (K112638).

Control Solutions

The control solutions are aqueous assayed solutions, containing buffered D-Glucose, viscosity-adjusting agent, preservatives and other non-reactive ingredients (dye). They contain no products of human origin. There are three levels of controls. One level of control (Level 2) will be supplied with the monitor kit and all three levels will be available for sale separately from the monitor. These controls are manufactured by Nova Biomedical and identical to those cleared for distribution with the predicate Nova Max One Blood Glucose Monitor System (K112638).

G. Summary of Technological Characteristics:

The Nova One Blood Glucose Monitor is the same device cleared in K112638 (Nova Max One Glucose Monitor System) and has the same fundamental scientific technology. The Nova One Blood Glucose Monitor is substantially equivalent to the Nova Max One Blood Glucose Monitor.

The Nova One Blood Glucose Monitor measures glucose electrochemically as described in K112638 (Nova Max One Glucose Monitor System). In the same manner, the magnitude of the current is proportional to the amount of glucose present in the sample, providing a quantitative measure of glucose in whole blood and control solutions.

H. Predicate Device:

K112638 - Nova Max One Blood Glucose Monitor System

K080641 - Home Diagnostics Inc. TRUEresult Blood Glucose Monitor System

I. Comparison to Predicate Devices:

The Nova One Blood Glucose Monitor is identical to the previously cleared Nova Max One Blood Glucose Monitor (K112638). It has the same fundamental scientific technology. The indication for use has been expanded to include whole venous and arterial blood, as well as capillary blood. No changes were made to any of the components of the system as compared to the cleared system (K112638). The Nova One Blood Glucose Monitor has the similar indications for use (whole venous and capillary blood) as the Home Diagnostics Inc. TRUEresult Blood Glucose Monitor System (K080641). The Nova One Blood Glucose Monitor is substantially equivalent to the Nova Max One Glucose Monitor System and the Home Diagnostics Inc. TRUEresult Blood Glucose Monitor System. Please see the table *Comparison of Predicate and Proposed Devices* below.

J. Performance Studies:

The performance of the Nova One Blood Glucose Monitor was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that medical professionals can obtain blood glucose results from venous/arterial blood that are substantially equivalent to the current methods for blood glucose measurements obtained from capillary blood and in the central laboratory.

K. Conclusion:

Results of laboratory and clinical testing demonstrate that the Nova One Blood Glucose Monitor produces results that are substantially equivalent to results obtained on the predicate device. The system performs as intended and raises no new safety or effectiveness issues.

Comparison of Predicate and Proposed device

Characteristic	Predicate - Nova Max One Blood Glucose Monitor System - K112638	Predicate - TRUEresult Blood Glucose Monitor System – K080641	Proposed - Nova One Blood Glucose Monitor System
Measuring Range	20-600 mg/dL	20-600 mg/dL	20-600 mg/dL
Operating Principle	Coulometric Electro-chemical Sensor	Amperometric Electro-chemical Sensor	Coulometric Electro-chemical Sensor
Intended Use	The Nova Max One Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. It is intended for single-patient home use and should not be used for testing multiple patients. It is intended for self testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The Nova Max One Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in fresh whole blood capillary samples obtained from the fingertip or alternative site testing (AST) on the forearm. AST on the forearm can be used only during steady-state blood glucose conditions. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on newborns.	The TRUEresult Blood Glucose System is intended for the quantitative determination of glucose in human whole blood taken from the finger or forearm. The system is intended to be used to assist the patient and Healthcare Professional in the management of diabetes. Healthcare Professionals may use the device to test venous whole blood; home use is limited to capillary whole blood testing. Not for neonatal use.	The Nova One Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous, arterial and fresh capillary whole blood from the finger and forearm. It is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a professional healthcare setting as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use, auto-disabling lancets. The Nova One Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on neonates. Alternative site testing on the forearm should be used only during steady-state blood glucose conditions. Nova One Blood Glucose Test Strips are for use with the Nova One Blood Glucose Monitors for quantitatively measuring glucose in venous, arterial and fresh capillary whole blood from the finger and forearm.
Hematocrit Range	25% to 60%	20% to 60%	25% to 60%
Sample type	Capillary blood from the fingertip, forearm	Venous blood and Capillary blood from the fingertip, forearm	Venous/Arterial blood and Capillary blood from the fingertip, forearm

Characteristic	Predicate - Nova Max One Blood Glucose Monitor System - K112638	Predicate - TRUEresult Blood Glucose Monitor System – K080641	Proposed - Nova One Blood Glucose Monitor System
Sample size	0.4 µL	0.5 µL	0.4 µL
Glucose Units	mg/dL	mg/dL	mg/dL
Sample application	Test strip capillary draw	Test strip capillary draw	Test strip capillary draw
Handheld meter?	Yes	Yes	Yes
Data storage	Up to 400 blood glucose and control solution tests	Up to 500 blood glucose and control solution tests	Up to 400 blood glucose and control solution tests
Analysis Time	4 seconds	4 seconds	4 seconds
Insulin Tracking	No.	No	No.
Power source	3 volt coin cell battery	3 volt coin cell battery	3 volt coin cell battery
Test Strip Ejector	Yes	No	Yes
Test Strips Active reagent:	Glucose Dehydrogenase - FAD	Glucose Dehydrogenase - PQQ	Glucose Dehydrogenase - FAD
Test Strip Calibration Coding	No User Input of Calibration code required	No User Input of Calibration code required	No User Input of Calibration code required
Accessories:			
Controls:	Liquid, 3 levels	Liquid, 3 levels	Liquid, 3 levels
Lancing Device:	Nova Reusable Lancing Device and Lancets	Reusable Lancing Device and Lancets	Nova Single Use Disposable Safety Lancets

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 20, 2012

Nova Biomedical Corporation
c/o Paul W. MacDonald
200 Prospect Street
Waltham, MA 02454

Re: k122435
Trade/Device Name: Nova One Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: II
Product Code: NBW, LFR, JJX
Dated: December 12, 2012
Received: December 17, 2012

Dear Mr. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director,
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122435

Device Name: Nova One Blood Glucose Monitor

Indications for Use:

The Nova One Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous, arterial and fresh capillary whole blood from the finger and forearm. It is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a professional healthcare setting as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use, auto-disabling lancets. The Nova One Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on neonates. Alternative site testing on the forearm should be used only during steady-state blood glucose conditions.

Nova One Blood Glucose Test Strips are for use with the Nova One Blood Glucose Monitors for quantitatively measuring glucose in venous, arterial and fresh capillary whole blood from the finger and forearm. The Glucose Monitor is calibrated to provide plasma equivalent results to laboratory methods. Nova One Glucose Test Strips are for testing outside the body (in vitro diagnostic use only). The Nova One Blood Glucose Monitor should only be used as directed. They are not intended for the diagnosis of or screening for diabetes, and are not intended for use on newborns.

Nova Max Control Solutions are intended for use with the Nova Max, Nova Max One and Nova One Blood Glucose Monitoring Systems as a quality control check to verify the accuracy of blood glucose test results. There are three levels of controls, (Levels 1, 2, 3).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K122435